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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,612	06/04/2001	Rebecca E. Cahoon	BB-1262	5030

7590 04/10/2003
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EXAMINER

BUI, PHUONG T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/10/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/857,612

Applicant(s)
Cahoon et al.

Examiner
Phuong Bui

Art Unit
1638



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 14, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-24, 27-31, and 33-38 is/are pending in the application.
- 4a) Of the above, claim(s) 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 27-31, and 33-37 is/are rejected.
- 7) ☒ Claim(s) 23 and 24 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other:

Art Unit: 1638

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed January 14, 2003. Claims 25, 26 and 32 have been canceled. Claims 36-38 are newly added. Claims 19-24, 27-31 and 33-38 are pending. In view of the newly added claims, the previous restriction has been modified to the extent below.

Group I, claim(s) 19-24, 27-31 and 33-37, drawn to a polynucleotide, chimeric gene, host cell, virus, plant, vector, method for transforming and first method of using.

Group II, claim(s) 38, drawn to a second method of using.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: These groups lack a corresponding special technical feature because these are two different methods of using a polynucleotide, wherein the first method is a method of altering expression levels and the second method is a method of isolating a polypeptide.

3. In the restriction election of January 14, 2003, Applicant elected Group I and SEQ ID NO:13 encoding SEQ ID NO:14 without traverse. Accordingly, claims 19-24, 27-31 and 33-37 are elected by original presentation and are examined in the instant application. Claim 38 is nonelected and will not be examined. This restriction is made FINAL.

Sequence Listing

Art Unit: 1638

4. Applicant's CRF and paper sequence listing have been entered. However, upon examination of SEQ ID NO:13 and its corresponding amino acid sequence SEQ ID NO:14, it is unclear what region of SEQ ID NO:13 encodes SEQ ID NO:14. Clarification is required.

Information Disclosure Statement

5. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 11, is attached to the instant Office action.

Drawings

6. Formal drawings are required in response to the instant Office action.

7. The following informality has been noted and requires correction in response to this Office Action. Since figures must be numbered separately, i.e. "Figure 1A," "Figure 1B," etc. , Applicant is required to amend the Brief Description of the Drawings in Applicant's disclosure accordingly to reflect the proper figure designations which are in formal drawings when drawings are submitted.

Claim Rejections - 35 USC § 112, second paragraph

8. Claims 27, 31 and 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 depends from claim 34. It would appear that Applicant intends for claim 27 to depend from claim 19.

Art Unit: 1638

In claim 31, “transgenic” should be inserted in “regenerating a transgenic plant” for consistency with the preamble.

In claims 33-35, which recites “gene”, “gene” implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. This does not appear to be Applicant’s intention, as evidenced by Applicant’s recitation of “A chimeric gene”. It is suggested that “A chimeric gene” be amended to “A recombinant DNA construct”.

In claim 35, “altering” should be amended to “increasing” because “altering” encompasses both increasing and decreasing, and it is unclear how the same method would do both. Further, it would appear that the expression step would result in increased polypeptide expression, and not decreased polypeptide expression. Also, claim 35 is an incomplete method claim because it does not result in an altered level of lecithin:cholesterol acyltransferase.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

9. Claims 19-22, 27-31 and 33-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims reciting 80-95% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass

Art Unit: 1638

mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass transcriptional activators from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and transcriptional activators from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

10. Claim 35 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increasing the level of lecithin:cholesterol acyltransferase polypeptide expression, does not reasonably provide enablement for altering the level of lecithin:cholesterol acyltransferase polypeptide expression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The breadth of the claim encompasses both increasing and decreasing the level of lecithin:cholesterol acyltransferase polypeptide expression in a cell. However, the steps set forth in the claims are only directed to expressing the acyltransferase and thus increasing the level of acyltransferase in a cell. Applicant does not teach how the same method can be practiced for both increasing and decreasing. While expression of

Art Unit: 1638

some proteins are known to inhibit additional expression of the same proteins --negative feedback inhibition-- such does not appear to be the case here, as neither Applicant nor the state of the prior art teaches that lecithin:cholesterol acyltransferase is sensitive to negative feedback inhibition. Applicant provided no working examples as to how the method can be practiced to increase polypeptide expression, and how the same method can be practiced to decrease polypeptide expression. While one skilled in the art can readily follow the steps set forth in the claims, it is highly unlikely that these steps would result in decreased lecithin:cholesterol acyltransferase polypeptide expression as encompassed by the claim. Accordingly, one skilled in the art cannot practice the claimed invention as commensurate in scope with the claims without undue experimentation. It is suggest that Applicant amend "altering" to "increasing" to obviate this rejection.

Remarks

11. Claims 23 and 24 would be allowable if rewritten as independent claims. SEQ ID Nos. 13 and 14 are free of the prior art. It is understood by the Office that the Clustal method of alignment of sequences uses the default parameters set forth on page 7 lines 25-26 of the specification.

12. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).


Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
April 6, 2003



PHUONG T. BUI
PRIMARY EXAMINER